Guidance for Industry and FDA

Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions

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Anesthesiology and Respiratory Devices Branch
Division of Cardiovascular Respiratory and Anesthesiology Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Christy Foreman, Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Christy Foreman at (301) 443-8609 Ext. 177.

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Introduction:

This guidance document describes a means by which indwelling blood gas analyzers may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate indwelling blood gas analyzer device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

This guidance document has been developed as a special control to support a change in classification from class III to class II. It identifies relevant material on clinical studies and labeling to include in a 510(k) premarket notification application. We intend it be used in conjunction with other identified special controls. All FDA requirements regarding premarket notification submissions are not repeated in this document. Please refer to the published Federal Register notice for other applicable guidance documents and standards.

Scope:

The scope of this document is limited to the clinical and labeling aspects for the following devices:

- Indwelling Blood Carbon Dioxide Partial Pressure Analyzer (21 CFR 868.1150, 73 CCC)
- Indwelling Blood Hydrogen Ion Concentration Analyzer (21 CFR 868.1170. 73 CBZ)
- Indwelling Blood Oxygen Partial Pressure Analyzer (21 CFR 868.1200, 73 CCE)

In addition to indwelling sensors, extracorporeal sensors which are associated with indwelling sampling catheters are also reviewed under these regulations and are within the scope of this guidance.

Clinical:

Clinical studies for this device should be conducted under the IDE regulations (21 CFR part 812). This device is a significant risk device under 21 CFR 812.3(m)(4) due to the risk of patient injury from the indwelling component of the device.

The following situations would generally warrant a clinical study in order to demonstrate equivalence with respect to clinical performance:

1. Development of a new technology, which FDA considers sufficiently different or novel from currently legally marketed technology.

2. Modification of the sensor, such as changing from electrochemical to fluorescence, altering the membrane located within the sensor, or modifying the dye used in the sensor.

3. Any modification made to the electronic, optical or software elements of the device, including the controller, interface cabling and data analysis unit, which may effect device performance.

4. A change in labeling which affects device use or performance. For example, extending the duration of use beyond previously cleared indications.

When conducting a clinical study, the device should be compared to a currently, legally marketed clinical laboratory blood gas analyzer. Well-controlled clinical laboratory measurements may be regarded as the actual value of the variable. The patient population should be of adequate size to permit reasonable confidence in the measure of precision (standard deviation of bias). Parameters relating to effectiveness include bias (measured result minus actual value), precision, correlation coefficient, and sensor drift over time. The data points should be presented in discrete time intervals to allow assessment of sensor performance over time. Equivalence may be established by comparing the results to the specifications of predicate indwelling devices. The population should include patients with a substantial range of variation, including hypercarbic and acidotic patients, and patients who are hypocarbic and alkalotic. These conditions may be found in patients who are hyperventilated or are subjected to permissive hypercapnia.

A typical study could be conducted as follows:

30 patients: 10 hypocarbic ($pCO_2 < 32$), 10 normocarbic and 10 hypercarbic ($pCO_2 > 60$). To include a patient in a particular subset, at least 2/3 of that patient's readings should fall within that subset.

Device and comparative measurements would be made every 12 hours (± 4 hours) for the duration of the sensor life. To support a duration of use, at least 50 percent of the patients should utilize the sensor for the maximum intended lifespan. Additional measurements may be taken as clinically indicated and should be included in the data set.

Labeling:

The following items are specific to this device class and should be included in the device labeling in addition to the requirements of 21 CFR 801.1:

- Intended use
- Duration of use
- Prescription legend per 21 CFR 801.109
- Calibration intervals and procedures
- Shelf life
- The results of *in vitro* testing and clinical testing in terms of:
  - Bias (measured result minus actual value)
  - Precision (standard deviation of bias)
  - Correlation coefficient
- Any adverse events occurring in the clinical studies, in addition to known potential adverse events, should be summarized in the labeling. The labeling should state the type and the frequency of event.
- Known limitations or interferences
- Performance specifications
- The sensor shall be labeled for single patient use, non-pyrogenic, with instructions not to resterilize. It seems unlikely that reusable sensors would be a commercially distributed device, however submissions for such devices would require specific labeling for reuse.